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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,246

10/16/2003

Chenera Balan

A-825

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7590

10/24/2005

AMGEN INC.

MAIL STOP 28-2-C

ONE AMGEN CENTER DRIVE

THOUSAND OAKS, CA 91320-1799

EXAMINER

BERNHARDT, EMILY B

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/688,246

Applicant(s)

BALAN ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claim 1-3, 11, 13, drawn to compounds, compositions where Q1-Q2 ring is piperazine and R4 is phenyl or naphthyl, classified in class 544, subclasses such as 370 and others as determined by the exact nature of Q3-Q6 ring system and substituted derivatives; class 514 subclass 254.06, etc.
- II. Claims 1-11 and 13, drawn to compounds, compositions where Q1-Q2 is piperazine and R4 is R<sub>c</sub>, classified in class 544, subclasses such as 360, 363 and many others based on the very least by the nature of R<sub>c</sub> choices as well as nature of Q3-Q6 ring system; class 514 subclasses 253.06, 253.09 etc.
- III. Claims 1-3, 11, 13, drawn to compounds, compositions where Q1-Q2 ring is piperidines (i.e. one of Q1/Q2 is N, the other is CH) and R4 is phenyl or naphthyl, classified in class 546, subclasses such as 199 and many others as determined by the exact nature of Q3-Q6 ring system and substituted derivatives; class 514 subclass 322, etc.

- IV. Claims 1-11 and 13, drawn to compounds, compositions where Q1-Q2 ring is piperidines (i.e. one of Q1/Q2 is N, the other is CH) and R4 is Rc, classified in class 546, subclass 194, etc. and other classes such as 544 and many subclasses based on the very least by the nature of Rc choices as well as nature of Q3-Q6 ring system; class 514 subclass 318, etc.
- V. Claims 1-3 and 11, drawn to compounds, compositions where Q1-Q2 ring is tetrahydropyridines (i.e. one of Q1/Q2 is N, the other is C) and R4 is phenyl or naphthyl, classified in class 546, subclass 273.4, etc. and other classes and subclasses as determined by the exact nature of Q3-Q6 ring system and substituted derivatives; class 514 subclass 338, etc.
- VI. Claims 1-11 and 13, drawn to compounds, compositions where Q1-Q2 ring is tetrahydropyridines (i.e. one of Q1/Q2 is N, the other is C) and R4 is Rc, classified in class 546, subclass 256 and other

classes/subclasses based on the very least by the nature of Rc choices as well as nature of Q3-Q6 ring system; class 514 subclass 333, etc.

- VII. Claims 1-3 and 13, drawn to compounds, compositions where Q1-Q2 ring is 1,4 diazepines and R4 is phenyl or naphthyl, classified in class 540, subclass 575; class 514 subclass 218.
- VIII. Claims 1-10 and 13, drawn to compounds, compositions where Q1-Q2 ring is 1,4 diazepines and R4 is Rc, classified in class 540, subclass 575 and other subclasses as determined at the very least by the exact nature of Rc rings which include 7- and 8-membered heterocycles; class 514 subclasses various.
- IX. Claims 1 and 13, drawn to compounds, compositions not provided for by I- VIII above, classified in classes various, subclasses various as determined by the size and nature of the Q1-Q2 ring as well as degree of unsaturation as well as remaining variables.
- X. Claim 12, drawn to multiple uses employing compounds of I-IX, classified in class 514, subclasses various.

XI. Claim 14, drawn to a process of making compounds of I-IX, classified in classes, subclasses various as determined by the nature of final products prepared.

If group IX is elected applicants must pick a specific Q1-Q2 ring and choices for R4 as was done for remaining groups.

**For any group elected applicants must also further elect a single species to which claims may be limited should generic claims be found not allowable.**

Based on species elected by applicant further restriction may be required by the receiving examiner at Q3-Q5 as well as at Rc based on the various classifications present for species within a single group.

If groups X is elected applicants must pick a single use for examination and a compound group must be elected .

The inventions are distinct, each from the other because of the following reasons: The compounds of I-IX relate to compounds of considerable structural dissimilarity in view of the varying and all encompassing choices permitted at all variables. There is no common core and additionally no structural feature(s) which never vary. Such compounds are diversely classified and are not art-recognized equivalents. Art which may anticipate or render obvious one of

these groups would not necessarily do the same for those remaining based on the structural dissimilarity of I vs II vs III, etc. as a whole.

Inventions I-IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case more than one use exists for instant compounds as evidenced by the many particular pharmaceutical uses being claimed.

Inventions I-IX and XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case applicants' compounds could be made by a well-known procedure for introducing piperazine at the 2-position of benzimidazole ring such as employing piperazine reactant with a 2-halogenated benzimidazole.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined

in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In view of its length the restriction requirement is being set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).



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Art Unit: 1624

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Emily Bernhardt  
Primary Examiner  
Art Unit 1624